Index №: 22 -cv-10883 (PKC)

United States District Court

SOUTHERN DISTRICT OF NEW YORK

DOUGLAS SCHOTTENSTEIN, MD AND SCHOTTENSTEIN PAIN AND NEURO, PLLC D/B/A NY SPINE

Plaintiff

–v–

UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, M.D., ACTING COMMISSIONER OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION IN HIS OFFICIAL CAPACITY ONLY

Nominal Defendants

EDWARD L. CAPLA; YOLANDA CAPLA; ORTHOGEN INTERNATIONAL GMBH; PROF. DR. PETER WEHLING; NINA BREIDENBACH; PETER NIEDERAU; AND "JOHN DOE, JANE DOE & ABC CORP. 1-10"

Defendants,

SECOND AMENDED VERIFIED COMPLAINT

RICHARD BRUCE ROSENTHAL, ESQ.
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VERIFIED AMENDED COMPLAINT

Plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, maintaining their principal office at 18 E. 48th Street, Suite 901, New York, NY 10017 (collectively "Plaintiffs" or "Plaintiff") bring this action through their attorneys to address their rights and interests pertaining to Regenokine (an autologous mode of medical treatment and drug to relieve traumatic injury and/or inflammation) that has been licensed to Plaintiffs, a conspiracy employing tortious interference and fraud by Defendant Orthogen International GMBH ("Orthogen") and fraud and conversion by the Capla Defendants, as defined herein to damage Plaintiffs, withhold vital information from the public and deliberately avoid regulatory oversight by The United States Food And Drug Administration ("FDA"), named herein insofar as their interests appear, all for which Defendants conspired and did deprive Plaintiffs of monies and business relations through fraud, tortious interference, violated contracts, secreted assets and diversion from Plaintiffs of professional athletes and other Regenokine patients:

JURISDICTION

1. This Court has diversity jurisdiction, pursuant to 28 U.S. Code §1332(a) in that this is a civil action where the matter in controversy exceeds the sum of $75,000, exclusive of interest and costs, Plaintiffs are domiciled in the State of New York maintaining their office at 18 East 48th Street, Suite 901, New York, NY 10017 and their residence at 168 Thompson Street, New York, NY 10012 while the Orthogen Defendants are domiciled in Germany

and maintain their office at Ernst-Schneider-Platz 1, 40212 Duesseldorf, Germany, and the Capla Defendants are domiciled in the State of Florida with a residence address at 2238 NW 62nd Drive, Boca Raton, FL 33496. The Court has personal jurisdiction over all parties named.

2. This Court also has subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1331 in that this is a civil action that raises federal questions arising under the Constitution, laws or treaties of the United States.

3. Further, the Court has jurisdiction under 28 U.S.C. §1367, over pendent state law claims that are wholly intertwined with the federal questions asserted herein such that neither can be fully resolved without reference to the other.

VENUE

4. Venue is proper in the United States and the Southern District of New York under 28 U.S. Code §1391(a)(2), in that Plaintiffs maintain their principal office herein, all Defendants do not reside in the same State and a substantial part of the events and omissions giving rise to the claims asserted herein occurred in this District.

5. Venue is also proper in this District for the Federal Question posed because Orthogen International GMBH sought to introduce a drug/treatment into the United States through Plaintiffs' practice in this District and conspired with the named defendants in this action to, *inter alia*, administer the reintroduction of blood back into similarly situated persons deprived of United States Food And Drug Administration oversight and regulation.

FEDERAL QUESTION AND EQUITY JURISDICTION

THE FORUM SELECTION CLAUSE IS UNCONSCIONABLE

6. This Honorable Court is being asked to fashion appropriate remedies and provide equitable relief by enjoining the international Orthogen Defendants from entertaining a suit in Duesseldorf, Germany based in part on somewhat related issues of fact and law, but which will result in extreme prejudice and irreparable harm to Plaintiffs in that they will be barred by the forum selection clause from asserting the claims set forth herein, the locus of this litigation with access to witnesses and evidence is in this District, and Orthogen's fraudulent conduct and tortious interference with the Schottenstein-Capla agreement that underlies the conspiracy of the Orthogen Defendants with the Capla Defendants is outside the scope of the License Agreement rendering the forum selection provisions in applicable hereto..

7. This case has meager connections to Germany, the Orthogen Defendants maintain a frequent presence in this District and throughout the United States, the underlying agreement for the Regenokine License was reached in this District, and the forum selection clause in the License Agreement is designed and intended to thwart the ability of Plaintiffs to litigate this matter, The License Agreement is a contract of adhesion in which Plaintiffs, unlike Orthogen, were not represented by legal counsel.

8. Orthogen concedes that the locus of this matter is in this District by having previously availed itself of this Court's jurisdiction in order to file a §1782 Petition *ex parte*

seeking leave to issue subpoenas to obtain documents and testimony to be used in its German litigation.

9. This case has public implications concerning the health and welfare of American citizens, and on that ground removal of this matter to Germany will violate and offend key public policies in this District that require the protection of the health, safety and welfare of American citizens where the implications of a matter primarily affect them..

10. Additionally, the Forum selection clause in the License Agreement is unconscionable in that it bars the assertion of any counterclaim against Orthogen in the present action it has filed in Germany, and which Plaintiff Dr. Schottenstein has moved to dismiss on grounds that he will for all practical purposes be deprived of his day in court, wherein Orthogen seeks injunctive relief under threat of a coercive financial penalty of $250,000 EUR per violation and bars the litigation of Plaintiffs' entire claims and defenses.

THE FEDERAL QUESTION CONCERNING REGULATION OF REGENOKINE BY THE FDA AFFECTS PLAINTIFFS' VITAL INTERESTS

11. The Orthogen Defendants have promoted and advertised Regenokine, a drug/treatment that gives rise to a likely basis for federal oversight due to the alteration and use of human blood but for which Orthogen Defendants bar the United States doctors, who administer such treatment, from seeking.

12. Defendant Orthogen conspired with the Capla Defendants to evade the assertion of regulatory jurisdiction including

investigation, testing and an approval process by the United States Food and Drug Administration over Regenokine, which engages in autologous procedures drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood, now a prepared drug, pharmaceutical or modality likely subject to regulation, through injection into the patient at the affected sites.

13. The Defendants, individually and collectively, used interstate wire communications in furtherance of this scheme that was done to avoid federal scrutiny and oversight and to further a conspiracy that deprived Plaintiffs of millions of dollars.

14. Defendants, individually and collectively, devised a scheme to defraud the Plaintiffs, used mail and wire to transfer and secret monies, some of which were unlawfully obtained.

15. Plaintiff Dr. Schottenstein, a double board certified doctor, was told by the Orthogen defendants, that the Regenokine® Program, was in compliance with all state, federal and international laws. Plaintiffs had no reason to suspect that the Orthogen defendants were deliberately evading regulation of Regenokine by the US FDA.

16. Plaintiff, Dr. Schottenstein, who started performing Regenokine treatments a decade ago, was not otherwise aware of the efforts Defendants, individually and collectively, would pursue to avoid accountability or FDA approval of a treatment that upon information and belief

has been licensed for patient use to one or more individuals that are not practicing physicians within this federal district.

17. The Defendants, individually and collectively, all contributed to an enterprise using mail and wire to secret monies, administer an unlicensed medicine/drug that relies on the reintroduction of blood back into the patient's body, create unlawful profits and transfer monies to Defendants Orthogen while avoiding any meaningful regulation or United States Food and Drug Administration oversight.

18. The United States FDA is named insofar as their interests appear and for this Honorable Court to declare that the administration of the Regenokine treatment does not violate any state or federal laws, that the autologous procedures in drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood will not subject the Plaintiffs to any criminal or civil liability.

19. Plaintiff seeks equitable relief insofar as he has the right to know whether autologous procedures in drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood into the patient as is done under the Regenokine treatment and drug program requires US FDA oversight or can subject the Plaintiffs to any criminal or civil liability in providing treatment thereunder.

JURY TRIAL DEMANDED

20. The Plaintiffs hereby demand a trial by jury on all issues so triable.

PRELIMINARY STATEMENT

21. This action is against defendant Orthogen, Professor Dr. Peter Wehling ("P. Wehling"), Nina Breidenbach ("Breidenbach") and Peter Niederau ("Niederau"), hereinafter, collectively the "Orthogen defendants," and seeks injunctive relief, compensatory and exemplary damages, and an accounting and constructive trust arising out of the claims asserted herein for tortious interference with the economic relationship and advantage of Plaintiffs with defendant Capla as well as for fraud, conversion , and a conspiracy with the Capla Defendants to defraud and take from plaintiffs a medical practice in which they owned at least 50%.

22. The foregoing conduct also involved Capla and his wife, defendant Yolanda Capla ("Y. Capla") (hereinafter, collectively referred to as the "Capla defendants,") from whom Plaintiffs are seeking compensatory and exemplary damages and an accounting and constructive trust arising out of the claims asserted herein for fraud, conversion, conspiracy, breach of fiduciary duty, breach of contract, breach of the implied covenant of good faith and fair dealing, , quantum meruit and unjust enrichment.

23. Defendants, individually and collectively, devised a scheme to defraud the Plaintiffs and others and used mail and wire to transfer and secret monies, some of which were unlawfully obtained.

24. In doing so, Defendants, individually and collectively, represented that they would seek and obtain full compliance with state and federal law regarding a blood treatment that, instead, they secreted and took pains to remove from oversight.

25. The Orthogen Defendants, individually and collectively, engaged in acts of fraud to cover up their knowing and willful participation in a scheme with intent to defraud the Plaintiffs, and interfere with their economically advantageous relationship with Capla.

26. The Capla Defendants, discussed further herein, through fraud and conversion conspired with the Orthogen Defendants to exclude Plaintiffs from the Regenokine License Agreement and convert the Regenokine medical practice in which Plaintiffs held at least a 50% interest. In doing so, the Capla Defendants took monies that should have gone to Plaintiffs, and distributed that money to themselves and other persons.

27. The relationship between Capla and Plaintiff Doctor Schottenstein was both confidential and fiduciary, and proved to be highly beneficial and remunerative ultimately earning nearly four (4) million dollars a year from this single practice.

THE PARTIES AND STATEMENT OF FACTS

28. Plaintiff Douglas Schottenstein, MD is a medical doctor licensed to practice in both the States of New York and Florida, specializing in Neurology and Pain Management. He is Board Certified in both specialties placing him in a rare group of elite medical professionals that have achieved this double Board Certification.

29. Due to Dr. Schottenstein's high profile in the medical community and his frequent appearances in the media to discuss professional issues, his professional activities garner attention.

30. Dr. Schottenstein operates his medical practice through plaintiff Schottenstein Pain and Neuro, PLLC doing business as NY Spine, which maintains its principal office at Suite 901, 18 East 48th Street, New York, NY 10017.

31. Defendant United States Food and Drug Administration ("FDA"), through its Center for Biologics Evaluation and Research ("CBER"), regulates biological products for human use under applicable federal laws, including the Public Health Service Act, 42 U.S.C. Section 201 et seq. and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 1 et seq. The FDA and CBER protect and advance public health by ensuring that biological products are safe, effective and appropriately used.

32. As a vital part of the foregoing purposes, the FDA and CBER are responsible for regulatory oversight of the blood supply within the United States.

33. FDA promulgates and enforces standards for blood collection and for the manufacturing of blood products, including both transfusible and reintoductable components of whole blood, pharmaceuticals derived from blood cells or plasma, and related medical devices.

34. Plaintiffs are Regenokine Licensees expected by Orthogen to administer Regenokine to patients with inflammation and/or traumatic injury to principal joints and critical sites in their bodies.

35. Plaintiff, through legal counsel and research, has learned of high profile prosecutions (e.g. Theranos) regarding those who, among other things, evaded US FDA review for the handling of blood even in the absence of the element of reintoductable blood as in Regenokine®

36. After a thorough review of this Honorable Court's Order, the finding that many years of this treatment does not give rise to an imminent harm, the Plaintiffs request that this Court declare that the autologous procedure and drug known as Regenokine involving the drawing of blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood will not subject Plaintiffs, or others, to US FDA oversight or prosecution.

37. Orthogen International GmbH is a German corporation with offices located at Ernst-Schneider-Platz 1, 40212 Duesseldorf, Germany. Orthogen is the Licensor of the autologous treatment and drug regimen known as the Regenokine® Program pursuant to which patients with specified injuries or conditions may be treated with the objective of reducing inflammation and promoting healing on an accelerated basis.

38. In its capacity as Licensor, Orthogen has made and continues to make appearances in the United States, including New York, both through in person visits by its representatives and numerous written and electronic communications and telephone calls to persons in the United States, including Dr. Schottenstein, regarding the licensing and promotion of the Regenokine® Program. Defendant Orthogen engaged in tortious interference and

fraudulent conduct regarding Plaintiffs and participated in the conspiracy with the Capla Defendants as alleged herein.

39. Defendant Dr. Peter Wehling is the creator of Regenokine and is affiliated with both Defendant Orthogen and its parent company, Orthogen AG. Dr. Wehling engaged in fraudulent conduct regarding Plaintiffs and participated in the conspiracy between the Orthogen Defendants and the Capla Defendants as alleged herein.

40. Defendant Nina Breidenbach is the former Managing Director of Defendant Orthogen and was active in that position at the time that the claims in this matter arose. She engaged in both tortious interference and fraudulent conduct regarding Plaintiffs and participated in the conspiracy between the Orthogen Defendants and the Capla Defendants as alleged herein. She remains employed by Defendant Orthogen and among other duties is responsible for training of Regenokine Licensees.

41. Defendant Peter Niederau is the current Managing Director of Defendant Orthogen. He engaged in fraudulent conduct regarding Plaintiffs and participated in the conspiracy with the Capla Defendants as alleged herein.

42. Defendants Dr. Wehling, Breidenbach and Niederau reside in Germany and maintain their office address with defendant Orthogen at Ernst-Schneider-Platz 1, 40212 Duesseldorf, Germany

43. Defendant Edward L. Capla ("Capla") has obtained a medical education, but is not licensed to practice medicine. On or about October 13, 2012, Plaintiff Dr. Schottenstein and Capla first entered into a Regenokine License

Agreement with Defendant Orthogen subsequently renewed through 2013 and 2014 and wrongfully terminated by a written notice issued by Defendant Breidenbach on behalf of Orthogen as part of the conspiracy between the Orthogen Defendants and the Capla Defendants to terminate Dr. Schottenstein's License and exclude him from the Regenokine Practice. Capla engaged in fraudulent conduct and conversion against Plaintiffs within the aforesaid conspiracy.

44. Defendant Yolanda Capla ("Y. Capla") is Capla's wife and a former employee of Plaintiff NY Spine providing laboratory services regarding the Regenokine Practice. Y, Capla conspired with defendant Capla to exclude plaintiffs from the right to practice under the Regenokine® Program License. In doing so, Y. Capla acted in violation of her fiduciary duty and duty of loyalty to plaintiffs, and with fraud deliberately shielding her activities from plaintiffs and making false statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to justifiably believe to his detriment that the Capla Defendants had accepted the termination of the Regenokine License and were going forward on a different path. These false statements were deliberately made to induce Plaintiffs to refrain from challenging the License termination and to establish a pretext to come to Plaintiffs' office to secretly remove key documents needed for the Regenokine Practice to be conducted with Capla and his brother-in-law Wasserman,

Defendants John Doe, Jane Doe and ABC Corp. 1-10 are fictional defendants intended to cover other wrongdoers in

this matter, whose identities are presently unknown, but who may become known in the course of discovery hereunder, and whom plaintiffs reserve the right to implead as defendants in this action.

REGENOKINE®

45. Commencing on or about October 13, 2012, having learned that Capla, who posed as a medical doctor, was not licensed to practice medicine, Orthogen entered into a License Agreement with plaintiff Dr. Schottenstein, as Licensee #1, and defendant Capla, as Licensee #2, thereby issuing to them a License with a specified term to utilize the Regenokine® Program and drug to treat patients.

46. This License Agreement and those that followed in 2013 and 2014 constituted not only a grant of permission by Orthogen to use Regenokine as a treatment modality, but also evidenced an agreement (the "Schottenstein-Capla agreement") between Dr. Schottenstein and Capla to administer Regenokine in the Schottenstein NY Spine Medicine Office, therein prescribing their respective duties as members of the resulting Regenokine practice, and providing for compensation with net revenues after paying royalties and expenses.

47. The 2014 License Agreement with Orthogen authorized Dr. Schottenstein and Capla to administer Regenokine at the Schottenstein NY Spine Offices in both New York City and Miami, Florida for a 12-month term automatically renewable in 12-month increments unless timely notice of non-renewal was given or there was a termination for cause.

48. The 2014 License Agreement was amended by a Side Letter Agreement, effective as of June 1, 2014, with the result that the 2014 License term was made perennial, requiring no further renewals, running until at least 2030 with the expiration of the Regenokine patents protecting the proprietary and confidential methods and knowledge on which the Regenokine® Program and drug are based.

49. As amended, the 2014 Orthogen License issued to Plaintiff Dr. Schottenstein and Defendant Capla could only be terminated by Orthogen on a for cause basis. Dr. Schottenstein as the treating physician and Capla as the administrator engaged in the Regenokine practice under the 2014 perennial License through May 31, 2020.

THE ORTHOGEN CAPLA CONSPIRACY

50. On information and belief, Capla and his wife, Y. Capla (collectively, the "Capla Defendants"), commenced a conspiracy with Orthogen and its operatives, Dr. Peter Wehling, Nina Breidenbach, and Peter Niederau (collectively, the "Orthogen Defendants") based upon an agreement under which the Capla Defendants engaged in Fraud and Conversion, and the Orthogen Defendants employed both Tortious Interference with the Schottenstein Capla agreement as well as Fraud, to exclude Dr. Schottenstein as a Regenokine Licensee and remove him as an owner of the Regenokine Practice.

51. The Orthogen Defendants were motivated to remove Dr. Schottenstein by a desire to avoid FDA regulation of Regenokine since the doctor had pressed the issue of whether Regenokine should undergo such regulation when it had not done so.

52. The Capla Defendants were motivated by greed to seek a better financial arrangement with Capla's brother-in-law Dr. Wasserman in the Regenokine Practice than they had with Dr. Schottenstein.

THE OVERT ACTS

53. The overt acts in this conspiracy by Orthogen included (i) the March 24, 2020 Termination Letter for Non-Renewal sent by Defendant Breidenbach to Dr. Schottenstein and Capla, where the 2014 License term was perennial and no renewal was required, (ii) the issuance of a new License to Capla and Dr. Wasserman excluding Dr. Schottenstein, (iii) misrepresentations by Defendant Dr. Wehling to Plaintiff Dr. Schottenstein that the non-renewal was based on a temporary internal policy to limit Regenokine practitioners to Germany until negotiations to sell the Regenokine Know-How were concluded at which time Dr. Schottenstein's License would be reinstated, (iv) requiring Dr. Schottenstein to provide Regenokine patient records and identities to Orthogen, which on information and belief were turned over by Orthogen to Capla and Wasserman to continue the Regenokine Practice, (v) making patient referrals to the Wasserman-Capla Regenokine Practice, and (vi) The misrepresentations made by Defendant Niederau in his August 3, 2022 letter to Dr. Schottenstein that Plaintiff had no Regenokine rights and is required to cease using the Regenokine name for any purpose.

54. These overt acts by the Orthogen Defendants exhibit Fraud through intentionally and knowingly false and misleading statements of present fact, made to induce reliance and on which Dr. Schottenstein justifiably relied

to his detriment and/or tortious interference with the Schottenstein-Capla agreement under which Plaintiffs had been operating the Regenokine Practice with Capla since 2012.

55. The overt acts in this conspiracy by the Capla Defendants include (i) arranging with the Orthogen Defendants on knowingly false grounds of non-renewal the termination of the 2014 License, (ii) withholding information from Dr. Schottenstein that Capla in his dealings with Orthogen as Practice administrator was using these communications to fraudulently advance his own interests at the expense of Plaintiffs' interests while posing as though he was engaging in his normal and usual activities within the Practice, (iii) Y. Capla's text message to Dr. Schottenstein shortly after the March 24, 2020 Termination Notice was received thanking him for his leadership and standards that enabled the Regenokine Practice to succeed, turning down his offer to continue the Practice with non-Regenokine procedures and methods, and advising they [the Capla Defendants] had decided to move forward on a different path thereby inducing Dr. Schottenstein not to challenge the termination, on which he justifiably relied to his detriment, (iv) Y. Capla arranging to visit the NY Spine Office in order to pick up personal items left in the Office and using this reason as a pretext for creating the opportunity to surreptitiously take key records needed to continue the Regenokine Practice with Wasserman, and (v) accepting the new Regenokine License with Wasserman then conducting the Regenokine Practice, in which Plaintiffs owned a 50% interest that Capla acquired by conversion, in the Wasserman Office.

56. The underlying torts by the Orthogen Defendants in the conspiracy include (i) tortious interference with the Schottenstein-Capla agreement and advantageous relationship thereunder as evidenced by the wrongful and false termination of the 2014 License and the issuance of the new License to Capla and Wasserman, and (ii) fraud evidenced by the deliberate and knowing misrepresentations of current fact by Defendant Dr. Wehling to Dr. Schottenstein regarding the false internal policy and the promise of reinstatement on which Dr. Schottenstein justifiably relied to his detriment.

57. The underlying torts of the Capla Defendants in the conspiracy include fraud as evidenced by (i) the withholding of information from Plaintiffs that Capla was arranging with Orthogen to wrongfully terminate the 2014 License and the issuance of a new License to Capla and Wasserman and (ii) Defendant Y. Capla's false text message to Dr. Schottenstein.

58. Dr. Schottenstein justifiably relied on the fiduciary relationship between Capla and himself that did not permit Capla's underhanded dealings with Orthogen resulting in the License termination as well as the text sent to him.

59. The Capla Defendants also engaged in conversion of the Regenokine Practice which was a tangible asset in which Plaintiffs owned at least 50%. In this regard Plaintiffs had legal ownership or a superior right to their ownership interest in the Regenokine Practice and Capla exercised wrongful dominion over that interest.

60. Through this conspiracy, Orthogen also sought to interfere with and deny plaintiffs the benefits of their economic

relationship with the Capla defendants, and to act fraudulently and deceitfully to cover up said conspiracy and prevent plaintiffs from taking action to challenge and remediate same.

61. Based upon plaintiffs' information and belief, on or about March 24, 2020, Orthogen in conspiracy with the Capla defendants and with specific intent to do so, wrongfully terminated the perennial License for the Regenokine® Program issued to plaintiff Dr. Schottenstein and defendant Capla, not on any "for cause" basis, but on the sole basis that the License was not being renewed. At all times pertinent to this illegal action and the underlying conspiracy by and between the Orthogen defendants and the Capla defendants, Orthogen and the other Orthogen defendants knew that they were tortiously interfering with plaintiffs' economically advantageous relationship with the Capla defendants that would result in substantial losses to plaintiffs in the millions of dollars.

62. Within days after the discontinuance of the Regenokine® Program License Agreement with Schottenstein and Capla, Orthogen in furtherance of the aforesaid conspiracy entered into a new Regenokine® Program License Agreement with defendant Capla and, his brother-in-law Wasserman.

63. After discontinuance of the Regenokine® Program License with Schottenstein, Orthogen directed persons in the United States to a Dr. Bradley Wasserman and/or Capla for Regenokine®.

64. On information and belief, Orthogen was motivated to take these steps in order to avoid the likelihood of regulation of Regenokine® by the FDA and CBER as a

drug or other regulated modality or device as a result of plaintiff Schottenstein's high profile arising from his extraordinary credentials, his reputation in medical circles and the media as an expert in the fields of neurology and pain management, his frequent consultations in broadcast and print media, and his expressed concerns over the absence of any effort by Orthogen to have Regenokine® officially reviewed.

65. Defendant Professor Dr. Peter Wehling ("P. Wehling"), maintaining an address with defendant Orthogen, is the founder and developer of the Regenokine® Program, and a principal stockholder in Orthogen AG, Orthogen's parent, with whom he has contracted in order to permit Orthogen to license and administer the Regenokine® Program. Wehling has had numerous contacts and communications with Dr. Schottenstein in the United States.

66. On plaintiffs' information and belief, in conspiracy with the other Orthogen defendants and the Capla defendants, Wehling actively and knowingly engaged in fraudulent and deceitful communications with Dr. Schottenstein with the specific intent to mislead Dr. Schottenstein, prevent him from learning of the foregoing conspiracy, and cause him to withhold action challenging the License non-renewal and to remediate the damages willfully being caused by Defendants.

67. In this regard, Wehling deliberately, fraudulently and deceitfully misinformed Dr. Schottenstein that the non-renewal of the License was merely the result of a change in Orthogen's internal policy to limit practice under the Regenokine® Program to German practitioners while Orthogen was engaging in discussions to sell all or a

portion of the Regenokine® Program rights to third parties.

68. Defendant Wehling fraudulently and deceitfully stated to Dr. Schottenstein that he would make good-faith efforts so that the License would be reissued to Capla and him promptly after the current negotiations were concluded.

69. Defendant Nina Breidenbach, maintaining an address with defendant Orthogen, is a former Managing Director of Orthogen and presently supervises and implements licensee training, adherence to operational criteria, reporting requirements, royalty payments and other licensee services within the Regenokine® Program.

70. At all relevant times, Breidenbach has physically travelled and continues to travel to New York City and other locations throughout the United States in relation to her responsibilities to the Regenokine® Program and to plaintiff Dr. Schottenstein as a Regenokine® Program Licensee.

THE CONSPIRACY AND EVASION OF U.S. REGULATION

71. On information and belief, Breidenbach actively conspired with the other Orthogen defendants and the Capla defendants with the express intent to interfere with plaintiffs' economically advantageous relationship with Capla, and through fraudulent and deceitful actions and/or omissions to deprive plaintiffs of the revenues earned under that relationship.

72. As part of the foregoing conspiracy, Breidenbach signed and sent Dr. Schottenstein and Capla the March 24, 2020

non-renewal notice thereby intending to discontinue the Regenokine® Program License Agreement issued to them.

73. On information and belief, Breidenbach joined in the conspiracy to disrupt the economically advantageous relationship that plaintiffs enjoyed with the Capla defendants, and thereafter participated in the fraudulent and deceitful conduct with the other Orthogen defendants to terminate that relationship and fulfill the objectives of the conspiracy by issuance of a new License to Wasserman and Capla.

74. Defendant Peter Niederau, maintaining an address with defendant Orthogen, is the current Managing Director of Orthogen. In furtherance of the foregoing conspiracy with the other Orthogen defendants and the Capla defendants, on August 3, 2022, Niederau signed and delivered a letter to Dr. Schottenstein refusing to provide any know-how or services under the Regenokine® Program, stating "that there is no valid licensing agreement between you [Dr. Schottenstein] and ORTHOGEN," and demanding that Dr. Schottenstein refrain from any offer of the Regenokine® Program to his patients and to immediately take other specifically designated actions to disassociate from the Program.

75. In preparing and sending this letter to Dr. Schottenstein, Niederau advanced the conspiracy in which he had joined, acted knowingly with fraud and deceit, and fully ratified the conspiracy between and among the Orthogen defendants and the Capla defendants.

76. Defendant Edward L. Capla, who previously maintained an office address at c/o Bradley Wasserman, MD, 125 East 63rd Street, New York, NY 10065, but now resides at 2238

NW 62nd Drive, Boca Raton, FL 33496, on information and belief, holds a medical degree from Hungary but is not licensed to practice medicine.

77. Nevertheless, Capla wrongly and unethically utilizes the title of "Doctor," thereby deliberately misinforming the public thereby causing members thereof to believe that he is a licensed medical professional when he is not.

78. Because he does not hold a medical license and cannot legally perform the duties required to participate as a Regenokine® Program treatment provider, Capla cannot be a direct licensee of the Regenokine® Program.

79. In or about 2012, Capla was named as a subordinate Licensee under an agreement with Orthogen to participate in the Regenokine® Program, subject to the direction and supervision by plaintiff Dr. Schottenstein, the primary Licensee to which the License was granted. The initial License was for a 2-year term subject to renewal by Orthogen.

80. At the outset of the initial License term, Plaintiffs and Capla formed a mutually beneficial economic relationship through their agreement to operate under the License, pursuant to which plaintiff Dr. Schottenstein administered Regenokine® Program treatments to patients and Capla focused on reporting requirements and calculation of royalty payments.

81. This nascent agreement proved to be highly beneficial and remunerative, and the practice administering treatments to patients under the Regenokine® Program grew exponentially to the point that the services of some of the other members of defendant Capla's family, that is his

mother and father Judith J. Capla, MD and Tomas Capla, DDS, and defendant Yolanda Capla, Capla's wife, were utilized to handle laboratory work responsibilities.

82. The initial License was renewed in or about June, 2014 for an additional 2-year term, but promptly thereafter, in or about July, 2014, the License was modified by a written Side Letter Agreement with Orthogen to have a perennial term "until the last of the REGENOKINE TREATMENT PATENTS have expired or the KNOW-HOW is no longer protected, whichever is later, unless earlier terminated as provided in this Article 10" [for cause].As a result of this modification, renewal of the License was no longer required, and the License could only be terminated for cause as delineated therein.

83. During the next six years, the Regenokine® Program practice within the relationship between plaintiffs and Capla grew to as many as 3,500 patients and yielded distributions to plaintiffs of nearly $2 million per year and a like amount to Capla in the form of wages , and with distributions to Judith Capla, Thomas Capla and Yolanda Capla for their services.

84. On information and belief, at some point in this time frame, in violation of his fiduciary duty and agreement with plaintiffs, Capla and his wife Yolanda began to conspire with the Orthogen defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

85. In doing so, Capla, and his wife Yolanda , acted with fraud and deceit deliberately shielding their activities from plaintiffs and making statements both verbally and in writing calculated to mislead plaintiffs thereby causing

Dr. Schottenstein to believe that all was in order within the agreement with Capla.

86. Orthogen was complicit in and engaged in such fraud by participating in and not informing Schottenstein of these communications.

BREACH OF CONTRACT

87. The Capla Defendants engaged in the breach of the Schottenstein-Capla agreement as manifested in both the 2014 License Agreement and eight (8) years of conducting the Regenokine Practice under that License.

88. Capla breached the contract by misusing his responsibility to communicate with Orthogen on administration matters and royalty payments within the Practice to, instead, benefit himself at Plaintiffs' expense by conspiring to wrongfully terminate the License, the issuance of the new License, and the takeover of the Regenokine Practice by conversion in the absence of any agreement with or compensation to Plaintiffs.

89. Orthogen breached the 2014 License Agreement by wrongfully terminating same in accordance with the Notice of Termination dated March 24, 2020 issued by Defendant Nina Breidenbach.

UNJUST ENRICHMENT AND QUANTUM MERUIT

90. Dr. Schottenstein provided patient treatment services to create the Regenokine Practice in which the Capla Defendants benefitted. Dr. Schottenstein's efforts were essential to the establishment of the Practice.

91. By taking the Regenokine Practice through conversion and failing to compensate Plaintiffs for their interest therein, the Capla Defendants have been unjustly enriched.

92. Dr. Schottenstein's services in establishing the Regenokine Practice were rendered with the expectation of receiving compensation for his services and the value of the Practice. These services were accepted by the Capla Defendants, who subsequently took over the Practice by conversion, but the reasonable value of Plaintiffs' 50% interest in the Practice has not been compensated.

ADDITIONAL FACTS RELEVANT TO PLAINTIFFS' CLAIMS

93. On information and belief, there came a time when the Capla defendants conspired amongst themselves and with Orthogen and the Orthogen defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License.

94. In doing so, both the Orthogen defendants and the Capla defendants acted with fraud deliberately shielding their activities from plaintiffs and making statements calculated to mislead plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with Capla.

95. In acting in this manner, the Orthogen defendants well knew that they were acting tortiously to interfere with the highly advantageous economic relationship by and between plaintiffs and Capla, and that their actions further constituted a breach of the fiduciary duties they owed to plaintiffs.

96. The Capla defendants through this conspiracy with the Orthogen defendants breached the agreement by and between Dr. Schottenstein and Capla as well as the implied covenant of good faith and fair dealing and their respective duties of loyalty to plaintiffs.

97. On or about March 24, 2020, defendant Orthogen acting through defendant Breidenbach, then Managing Director, and fully supported by defendant Wehling, issued a letter to Dr. Schottenstein and defendant Capla advising that the License under the Regenokine® Program was to be terminated by May 31st, 2020 on the basis of non-renewal in accordance with the June 1st, 2014 License Agreement.

98. The March 24, 2020 letter did not refer to any for cause basis for Dr. Schottenstein's termination.

99. On information and belief this March 24, 2020 letter was issued to achieve the purpose of the conspiracy between the Orthogen defendants and the Capla defendants.

100. Moreover, although not mentioned in the March 24, 2020 letter, on information and belief, the arrangement to issue a new Regenokine® Program License to defendant Edward L. Capla and Dr. Wasserman to the exclusion of plaintiffs had already been agreed upon.

101. The March 24, 2020 letter constituted an illegal action by defendant Orthogen, issued in breach of the controlling Side Letter Agreement dated July 9, 2014 but expressly related back to and effective as of June 1, 2014, and said termination was void *ab initio*.

102. Shortly after the receipt of the March 24, 2020 letter defendant Y. Capla sent Dr. Schottenstein the following text message after Dr. Schottenstein, still

unknowledgeable about the conspiracy and the arrangement engineered by Orthogen and Capla, suggested that they continue their practice of autologous remedies outside of the Regenokine® Program using methodologies that did not incorporate or rely upon the Regenokine® Know-How:

> We wanted to express our deep gratitude and appreciation to you for all you have done for us and Regenokine. What we have accomplished as a team is remarkable and without you it would never have happened. You're an amazing person to work with and your tireless effort and care has made our jobs so much easier and more enjoyable. Your time, support, and cooperation we value a lot. Your exemplary work approach is unsurpassable. Much of the success of our team is because we all had the same mentality – hard work leads to success. Thank you from the bottom of our hearts for being a great colleague and never letting us settle for anything less than best. We appreciate your offer but we decided to move forward on a different path. Wishing you only the best forever and lots of continued success in your practice. I would like to come on Friday evening when you are done with patients to pick up our belongings. Let me know if this works.

The foregoing text message was deliberately and knowingly false and intended to induce Dr. Schottenstein to withhold any challenge to the termination of the License and to establish a false pretext to visit the NY Spine Office for the actual and intended purpose of secretly taking from that office key documents needed to continue the Regenokine Practice with Wasserman. Doctor Schottenstein justifiably relied upon this text message to his detriment.

103. Thereafter, Dr. Schottenstein was informed by defendant Wehling, the founder of the Regenokine® Program treatments, that the termination reflected a change in Orthogen's corporate policy pursuant to which Orthogen was limiting its Regenokine® Program licensing to practitioners in Germany as it proceeded to negotiate the sale of the program rights.

104. Defendant Wehling further informed Dr. Schottenstein that as soon as the Regenokine® rights were sold, Dr. Schottenstein would be offered an opportunity to relicense his Regenokine® practice.

105. These statements made to Dr. Schottenstein by defendant Wehling were calculated to cover up Orthogen's fraudulent and tortious conduct.

106. The foregoing communications from defendants Capla and Y. Capla and defendant Wehling to Dr. Schottenstein were fraudulent, and solely intended to convince Dr. Schottenstein that nothing untoward had occurred and to deter him from taking any formal action to challenge the failure to renew his License.

107. As an honest and trusting person, not disposed to suspicion of bad acts on the part of those with whom he deals, and relying upon the communications that he received from defendants, which subsequently proved to be intentionally misrepresented and fraudulent, Dr. Schottenstein justifiably relied thereon and initially cooperated in suspending his Regenokine® practice to his detriment..

108. In the following months, however, Dr. Schottenstein repeatedly sought to re-establish his License with Orthogen without success.

109. In the interim, however, Dr. Schottenstein learned that Orthogen had entered into a new License agreement with defendants Wasserman and Capla.

110. In or about mid-2022, Dr. Schottenstein assigned to legal counsel the task to review the non-renewal of his Regenokine® License and defendant Orthogen's issuance of a new License to Wasserman and defendant Capla.

111. Upon review of the License documentation, it became apparent that the July, 2014 Side Letter Agreement had created a perennial License no longer subject to renewal and terminable only for cause. On that basis, it was clear that the March 24, 2020 termination notice was void *ab initio* and Dr. Schottenstein's License had never been terminated.

112. On or about July 28, 2022, and then again on August 3, 2022, Dr. Schottenstein communicated with defendant Orthogen requesting the reinstatement of his License and all benefits to which he was entitled thereunder.

113. On August 3, 2022, defendant Peter Niederau, the current Managing Director of defendant Orthogen, joined the conspiracy and continued Orthogen's tortious and fraudulent conduct by issuing a letter to Dr. Schottenstein denying his requests and stating, "In light of the fact that there is no valid licensing agreement between you and ORTHOGEN, we request for you to refrain from any offer of the Regenokine® Program to your patients and to immediately take the website 'www.regenokineperformance.com'

> offline as well as seize (sic; cease) all public relations actions related to or in context of [the] Regenokine® Program. Furthermore, from our point of view 'www.regenokineperformance.com' website and its content is in violation of ORTHOGEN IP rights (Trademark, Patents, Know-How rights) and may violate at the same time US-laws." The Niederau letter further threatened Dr. Schottenstein that Orthogen's "attorneys will approach you in the upcoming days to substantiate our legal claims."

114. In immediate response to the Niederau letter, on August 3, 2022, counsel for Dr. Schottenstein issued a letter to defendant Niederau baldly stating that his position is in error, and that he needed to put Orthogen's attorneys in contact with legal counsel for Dr. Schottenstein.

115. Realizing that their scheme had now been uncovered, on August 8, 2022, Klaus Wehling, who purports to be a legal counsel for defendant Orthogen, communicated by e-mail conceding that Article 2 of the July, 2014 Side Letter Agreement "provides that Dr. Schottenstein is in principle granted a contract term until 2030 (patent term) Thus, it appears that the contract cannot be terminated without cause."

116. In a subsequent e-mail, Klaus Wehling stated, "the termination of the License Agreement in 2020 was invalid because ORTHOGEN's 2014 License Agreement in conjunction with the 2014 Supplemental Agreement provided that the term of the agreement should run until the end of the patent or know-how term (cf. Art. 2 of the Supplemental Agreement)….There was therefore agreement among all parties that the current contract had not been terminated and is therefore still valid."

117. These statements made by Klaus Wehling constitute an admission binding defendant Orthogen to the Klaus Wehling statement that the Schottenstein License was never terminated even though the actions of Orthogen destroyed the economically advantageous relationship of plaintiffs with defendant Capla and their income therefrom, thereby precipitating Dr. Schottenstein's loss, at that time, of two years of Regenokine® revenue approximating $4 million.

118. Moreover, since the License's perennial term would extend for at least eight (8) more years through the year 2030, Dr. Schottenstein continues to lose revenue, and is at risk of losing nearly an additional $16 million even before an upward adjustment of that loss calculation for additional growth in the practice, inflation and other applicable factors.

119. Recognizing that Orthogen's unjust position had literally cost Dr. Schottenstein the enormous losses he sustained, Klaus Wehling promptly proposed that Dr, Schottenstein would be identified as an expert in Regenokine® treatments, prominently featured on what he described as a universal landing page, and receive referrals of Regenokine® patients on an exclusive basis in the greater New York and Miami, Florida areas.

120. From the original License issuance in 2012 up to the time of the alleged termination in March, 2020, Dr. Schottenstein had received all of his Regenokine® patients from referrals by Orthogen.

121. Understanding that Dr. Schottenstein's License extended through 2030 and possibly longer should Orthogen continue to develop innovations for Regenokine®

protectable by patent, plaintiffs decided to attempt to mitigate their damages through the promise of exclusive referrals without waiving any of their other remedial alternatives.

122. Nevertheless, despite Dr. Schottenstein undergoing updated training on the know-how in mid-September, 2022 and passing audits of his laboratory facilities and materials in the same time frame, no patient referrals from defendant Orthogen were forthcoming.

123. In response to communications from and on behalf of plaintiffs seeking patient referrals, Klaus Wehling countered with statements that there were irregularities in the reporting and royalty payment calculations under the 2014 License prior to the March 24, 2020 letter announcing non-renewal.

124. No such complaint was ever provided to Dr. Schottenstein prior to the illegal termination notice of March 24, 2020 that proceeded solely on a failure to renew, which was not applicable, and not on any for cause basis. Moreover, these alleged irregularities in reporting and royalty payments are alleged to have started in 2017, but the illegal termination letter did not issue until three years later in 2020.

125. In that three year period, Orthogen never communicated to Dr. Schottenstein that such problems existed, not once, even though Dr. Schottenstein was Licensee No.1 and thereby responsible for the supervision of Capla and all activity conducted under the License.

FACTS RELEVANT TO THE COVER UP, EQUITABLE RELIEF REQUESTED AND IMMINENT HARM

126. The fact that the Orthogen defendants actively misrepresented to Dr. Schottenstein the reason for the non-renewal, while going behind Dr. Schottenstein's back to enter into a substitute License Agreement with Defendant Capla, a non-doctor and the known likely wrongdoer in the alleged misreporting and under-payments of royalties, and his brother-in-law, Dr. Wasserman, who had virtually no experience in autologous treatment protocols or pain management, highlight the bad faith, fraud, conspiracy and tortious interference by Orthogen and its principal actors.

127. In an e-mail dated November 7, 2022, Klaus Wehling at last partially addressed the issue of referrals as follows:

> As for referrals, ORTHOGEN can't say much about them. In the past, ORTHOGEN has not received any patient inquiries from patients, so ORTHOGEN could never make any recommendation here. As far as the future is concerned, ORTHOGEN would – in case of a corresponding request – name the LICENSEES that offer the Regenokine® Program in the requested area(i.e., e.g. USA). Thus, there would be neither a preference nor a Disadvantage of any physician from ORTHOGEN. In any case, every patient will look at the homepages of the offering physicians on the Internet and decide who to go to.

128. Klaus Wehling's statement in this regard was not only wholly inaccurate regarding Dr. Schottenstein's referral experience from Orthogen during the period from 2012 to 2020, but was also an outright lie.

129. Dr. Schottenstein had been informed by a number of his prior Regenokine® patients that they had been referred by Orthogen personnel, including defendant Niederau, to Wasserman.

130. Contrary to Klaus Wehling's misrepresentation, Orthogen was referring former patients of Dr. Schottenstein to Wasserman for Regenokine® treatments while Dr. Schottenstein's License had not been cancelled, the patients being referred to defendant Wasserman were Dr. Schottenstein's patients, and defendant Orthogen was actively denying and covering up the referral practices in which it was presently engaged.

131. On November 10, 2022, plaintiff Dr. Schottenstein, disgusted with the lies, fraudulent conduct, tortious interference and conspiracy engaged in by the Orthogen defendants, addressed an e-mail to Klaus Wehling, defendant Breidenbach and defendant Peter Wehling demanding in blunt language that they restore to plaintiffs the Regenokine® Program practice that defendant Orthogen had tortiously taken away and in breach of the 2014 License..

132. In response, by letter dated November 28, 2022 from legal counsel, Orthogen, first contended that the March 24, 2020 letter effectively terminated Dr. Schottenstein's License, a position that wholly ignores the admissions binding Orthogen that the Schottenstein License was never terminated and had been fully reinstated, then asserted that the reinstated License was terminated once again, this time for cause.

133. In that letter dated November 28, 2022, defendant Orthogen through its legal counsel threatened to

commence litigation against plaintiffs in the court of Duesseldorf, Germany. Plaintiffs seek injunctive relief from this court to stay defendant Orthogen and the other Orthogen defendants from commencing and/or proceeding with such litigation in Germany, considering that this case includes the FDA for declaratory relief of the underlying federal question common to all the claims asserted as well as the Orthogen defendants and the Capla defendants comprising all of the parties needed to resolve the claims set forth hereunder, and where this matter addresses claims based upon tortious interference, fraud, breach of fiduciary duty, breach of the duty of loyalty, conspiracy, an accounting, unjust enrichment and constructive trust to remedy the wrongful acts that occurred within the jurisdiction of this Court.

134. As an example of Regenokine® patients that they had been referred by Orthogen personnel directly, on March 3, 2022, Defendant Peter Niederau sent a message to a client or potential client stating that "Dr. Bradley Wasserman has answered regarding the Regenokine Program prices in his practice. Price for one knee in his practice is 10.000$, bilateral knee injection is 15.000$."

135. The foregoing facts raise clear inferences that Orthogen issued the March 24, 2020 termination notice to Dr. Schottenstein not due to oversight or mistake, but with an intention to evade federal regulation of Regenokine® and to tortiously interfere with the economically advantageous relationship with Capla that cannot be restored.

136. Orthogen was part of the conspiracy with the Capla Defendants seeking to wrongly deprive plaintiffs of the benefits of the Schottenstein Regenokine® Program

License, which conspiracy could not succeed in the absence of Orthogen's tortious interference with the Schottenstein-Capla agreement by wrongfully and illegally issuing the March 24, 2020 notice of termination on the basis of a failure to renew.

137. In this process, Orthogen and the other Orthogen defendants engaged in the delineated fraudulent activities designed to both evade federal regulatory jurisdiction and hurt Dr. Schottenstein economically.

138. The Orthogen defendants engaged in fraud to gain Dr. Schottenstein's cooperation with their nefarious ends through deliberate and knowing false statements on which they intended that he rely, and when given the chance to restore Dr. Schottenstein's Regenokine® practice, they actively worked against him in favor of Defendant Capla and Dr. Wasserman, then deliberately lied to conceal it.

139. The conduct of the Orthogen defendants as set forth in this Complaint is and continues to be scurrilous and outrageous meriting both compensatory and punitive damages.

140. In violation of their fiduciary duty and agreement with plaintiffs, Capla and Y. Capla also violated their duty of loyalty to plaintiffs, began to conspire with the Orthogen defendants to exclude plaintiffs from the right to practice under the Regenokine® Program License held by Dr. Schottenstein.

141. In doing so, they also acted with fraud, breached their fiduciary duty, breached the agreement between plaintiffs and Capla, and entered into a conspiracy by untruthfully informing plaintiffs they intended to undertake a real

estate opportunity, and withheld from plaintiffs the material information that they had negotiated a substitute Regenokine® Program License to be issued to Wasserman and Capla, and under which they intended to exclusively operate the Regenokine® Program practice in which Dr. Schottenstein held an equal, if not exclusive, interest.

142. In this manner, defendant Capla with Y. Capla deliberately shielded their activities from plaintiffs thereby causing Dr. Schottenstein to believe that all was in order within the agreement with Capla.

143. As a result, of their willful, deliberate and outrageous conduct, defendants Capla and Y. Capla have been unjustly enriched to the detriment of plaintiffs in taking over and converting the operational, property and revenue interests, and cash flow from the Regenokine® Program practice they continue to presently operate, and to which plaintiffs claim at least a 50% interest together with claims for prior compensatory damages incurred, future compensatory damages to be incurred, and punitive damages arising from the scurrilous and outrageous conduct of these defendants.

144. Plaintiffs are entitled to establish a constructive trust over all assets, patient lists, treatment records and earnings of defendants Capla and Y. Capla derived from the Regenokine® Program practice, in which they have and continue to be wrongly engaged.

145. Defendant Orthogen has failed or refused to qualify to do business in New York. Additionally, to plaintiffs' information and belief, neither defendant Orthogen nor the other Orthogen defendants maintain assets within the

State of New York sufficient to satisfy the monetary claims asserted against them herein.

146. On information and belief, plaintiffs assert that defendant Orthogen maintains an automatic transfer agreement and arrangement with its parent company, Orthogen AG, under which funds received by defendant Orthogen are immediately transferred to Orthogen AG, thereby creating additional unwarranted obstacles to the satisfaction of any judgment awarded to plaintiffs against the Orthogen defendants in this action.

147. Furthermore, the Orthogen defendants have exhibited a pattern of fraudulent and otherwise outrageous tortious conduct as delineated in this Complaint giving rise to a high probability of compensatory and punitive damages being found against them.

148. In light of the foregoing, plaintiffs are further entitled to establish a constructive trust over all funds derived from the aforesaid Capla-Wasserman Regenokine® Program practice and/or any other such practice located within New York State that would otherwise be payable to defendant Orthogen as royalties or other fees in order to maintain these assets of the Orthogen defendants within the jurisdiction of this Court to satisfy the claims asserted against them herein.

DECLARATORY JUDGMENT CLAIMS
DECLARATORY JUDGMENT AGAINST DEFENDANT ORTHOGEN INTERNATIONAL GMBH AND DEFENDANT UNITED STATES FOOD AND DRUG ADMINISTRATION

149. Plaintiffs repeat the allegations set forth in the above paragraphs and incorporate them by reference in this Count as if set forth at length herein.

150. Defendant Orthogen International GmbH ("Orthogen") is the international Licensor and distributor of Regenokine®, which it identifies as a treatment program designed to reduce inflammation and promote healing in various joints of the body, including the spine, knees and shoulders.

151. Orthogen takes great pains to differentiate Regenokine® from a drug that is regulated by Defendant United States Food and Drug Administration ("FDA").

152. Orthogen licenses and distributes Regenokine proprietary methods and procedures, which it identifies as "Know How," throughout the United States including, but not limited to the States of New York, Texas, Florida and California.

153. Orthogen has deliberately constructed a scheme built into its License Agreement to elude regulation and oversight by the FDA through a high level of Regenokine® concealment under an impenetrable cloud of internal proprietary regulation.

154. This became apparent when the fraudulent scheme between Defendants was exposed revealing the question of whether regulatory oversight should be imposed concerning autologous procedures involved in drawing blood from patients with inflammation from trauma or

other causes, treating that blood with proprietary substances and processes and then reintroducing that blood back into the patient.

155. Orthogen Licensees can neither publicly discuss nor make any reference to Regenokine® in the absence of an advance submission to and approval by Orthogen's trademark and patent counsel located in Washington, D.C. in order to prevent any substantive disclosure that could trigger the imposition of regulatory measures over the "Know How."

156. On information and belief, Orthogen has never sought or made submission to the FDA to determine whether or not Regenokine® is subject to regulatory review, administrative control and/or investigation, testing and the process for approval by the FDA.

157. Regenokine® is wholly elective.

158. Regenokine® is neither used nor intended as a last chance remedy for terminal patients facing the inevitable that are desperate for any answer and who are therefore prepared to assume any risk.

159. To the contrary, Regenokine® is offered at a high price on a cash only basis, is not reimbursable by health insurance, and is thereby shielded from questioning and attention that could result in regulation.

160. Orthogen does not advertise Regenokine®, but markets it through a detailed and developed system fueled by word of mouth among elite professional athletes and other wealthy patrons that need or otherwise desire to accelerate healing from physical trauma or inflammation arising from other causes. As such, these candidates for treatment under

Regenokine® anticipate that they will incur no significant risk thereunder.

161. For example, Orthogen's online presence and advertisement through the world wide web can be accessed here: https://www.regenokineusa.com/ and https://try.theregenokineprogram.com/nyc-2/.

162. Orthogen states that "The Regenokine® Program has been trusted by athletes and pro teams as their preferred treatment for joint and back pain… Treating players in 30+ professional sports teams…Athletes from the NFL, NBA, MLB, PGA, UFC, NHL, and other leagues."

163. In Orthogen's disclaimer portion of the website (https://theregenokineprogram.com/disclaimers.html), it states "This information does not substitute for a personal consultation with a licensed Regenokine® Program Doctor. The site's goal is to help you decide whether to seek an appointment with a licensed Doctor who can evaluate your pain and work with you to decide if the Regenokine® Program or other treatment is right for you."

164. The Orthogen disclaimer, *id.*, further states "Regenokine® USA connects patients with doctors who have been trained in the Regenokine® Program."

165. In this environment, it is highly likely that the representations made by Orthogen and its Regenokine®, licensees are overstated and misleading.

166. Defendant Orthogen, however, has licensed Regenokine in the United States to one or more individuals that are not licensed to practice medicine.

This Court, in determining the treatment had been utilized for a number of years, narrowed the Federal Question for

which Plaintiffs respectfully request declaratory relief: Are the autologous procedures in drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood into the patient subject to US FDA oversight?

SUBSTANTIAL FEDERAL QUESTION CONCERNING ORTHOGEN AND REGENOKINE® REGULATION

167. Plaintiffs, as this Honorable Court decided, have the right to know if Regenokine® is subject to US FDA regulation, insofar as they should know if they are subject to liability for administering Regenokine®, especially after several high profile US FDA prosecutions for blood treatments.

168. Defendant United States Food and Drug Administration ("FDA"), through its Center for Biologics Evaluation and Research ("CBER"), regulates biological products for human use under applicable federal laws, including the Public Health Service Act, 42 U.S.C. Section 201 et seq. and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 1 et seq. and regulations promulgated thereunder.

169. The FDA and CBER protect and advance public health by ensuring that biological products are safe, effective and appropriately used and stored.

170. As a vital part of the foregoing purposes, the FDA and CBER are responsible for regulatory oversight of the blood supply and the use, storage and treatment of blood within the United States.

171. In this regard FDA promulgates and enforces standards for blood collection, testing, and for the manufacturing and storage of blood products, including both transfusible and reintoductable components of whole blood,

pharmaceuticals derived from blood cells or plasma, and related medical devices.

172. Federal regulations require among other standards that a person be free from and avoid any disease transmissible by blood transfusion or reintroduction, in so far as can be determined by health history and examination as well as the way in which blood is treated, stored and administered. Donors and recipients are required to be informed about potential risks and are further required to answer questions about factors that may have a bearing on the safety of their blood and its subsequent administration.

173. FDA has recently required investigation, testing, and a rigorous approval process for other autologous procedures, namely two blood tests, Guardant360 CDx and Foundation One Liquid CDx, known as liquid biopsies, intended to guide treatment decisions for people with cancer. *See*, *FDA Approves Blood Tests That Can Help Guide Cancer Treatment*, US Gov. (December 26, 2022); accessible at:https://www.cancer.gov/news-events/cancer-currents-blog/2020/fda-guardant-360-foundation-one-cancer-liquid-biopsy.

174. The FDA regulatory process regarding these procedures resulted in the subject tests being approved for only certain cancers, and, in regard to the specified cancers only, these procedures can be used to guide the selection of a targeted cancer therapy.

175. The FDA also played a critical role in bringing to light the Theranos scandal engineered by its CEO Elizabeth Holmes and its Chief Operating Officer Sunny Balwani,

when it ruled that nanotainers the company created to collect blood were an "unapproved" medical device.

176. It was through counsel and the suggestion that Orthogen had not been forthcoming with plaintiffs about the procedure that used the good name, repute and certifications of Dr. Schottenstein, that plaintiffs became aware that something he was administering in 2012 as a double-board certified licensed medical doctor may cause injury, harm or death if suddenly administered by unlicensed and untrained professionals, especially if the treatment was not approved by the US FDA.

177. Theranos had claimed it would revolutionize blood testing with technology that could analyze tiny amounts of blood to diagnose a wide range of medical conditions which resulted in Theranos entering into mega deals with Walgreens and Safeway for the sale and distribution of its Edison testing device. The device did not work causing Theranos to rely upon blood testing that could not be validated and to void as inaccurate testing results that questioned the capabilities of the device without disclosure resulting in a "massive fraud" subsequently prosecuted. *See,* Danielle Kirsh, *Former Theranos lab director takes the stand, says Elizabeth Holmes was 'nervous' amid blood test inaccuracy concerns*, Mass Device (September 27, 2021), last accessed on December 26, 2022: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-approved-application-biological-products-human-blood-and-blood-components-intended.

178. By characterizing Regenokine®, as a treatment program as opposed to a drug, Orthogen has deliberately avoided the FDA and CBER approval process.

179. Plaintiffs are Regenokine® Licensees expected by Orthogen to administer Regenokine® to patients with inflammation and/or injury to principal joints and critical sites in their bodies. Plaintiff Douglas Schottenstein, MD, a Regenokine® Licensee, is also a licensed physician in the States of New York and Florida and is Board Certified in both Neurology and Pain Management. Plaintiff NY Spine is the entity through which Dr. Schottenstein engages in his medical practice and is also licensed by Orthogen to administer Regenokine® to his patients.

180. Plaintiffs have been placed at risk of punishment by the actions and omissions of the Orthogen defendants in deliberately avoiding FDA oversight for Regenokine®.

181. Plaintiffs are concerned that Orthogen has eluded FDA and CBER oversight and regulatory investigation, testing and approval to the likely detriment and imminent irreparable harm of their patients.

182. Plaintiff Dr. Schottenstein is further concerned that he may be subject to punishment for engaging in and promoting Regenokine® without obtaining a determination under applicable law and federal regulations designed for the protection of parties comprising the public at large, whose members are not before this Court.

183. Plaintiffs are aware that FDA and CBER regulate the collection of blood and blood components used for transfusion and reintroduction or the manufacture of pharmaceuticals derived from blood and blood components, such as clotting factors, storage containers, storage procedures and establishing standards for the products themselves.

184. FDA further regulates related products such as cell separation devices, blood collection containers and other screening tests that are used to prepare blood products to ensure safety.

185. Under Title 21 of the Code of Federal Regulations 640.120, the Director, Center for Biologics Evaluation and Research has direct administrative and regulatory oversight regarding blood, blood components and/or blood products. Both licensed and unlicensed blood establishments must submit to this administrative and regulatory oversight under 21 CFR 601.12. *See*, **Exhibit 3**, Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture, December, 2014, Final Guidance. Plaintiffs are entitled to a ruling regarding whether there is a regulatory requirement for Regenokine®. They are not required to risk and possibly incur punishment in order to learn the status of Regenokine® in regard to regulatory requirements.

186. As a result of Plaintiff's expression of their concerns to Orthogen, it has taken retaliatory measures against Plaintiffs attempting to terminate Plaintiffs' Regenokine® License.

187. Plaintiffs maintain standing under this Count both as a result of their concerns for their patients and as medical professionals sworn to do no harm for the general safety and welfare of the general public, as targets of Orthogen's attempt to terminate their Regenokine®, License by reason of their concerns, and their right to seek a determination of this regulatory issue before risking

punishment through the administration to patients of tfe Regenokine Program and drug..

188. Plaintiffs contend that Regenokine® is not merely a treatment method, but is a drug or other substance subject to regulation, investigation, testing and approval or rejection for use under FDA and CBER protocols that are mandated for the safety of the general public and the individual patients that seek Regenokine® for their inflammation, pain and needs for healing from traumatic and other circumstances.

189. The foregoing applicability of the Public Health Service Act, 42 U.S.C. Section 201 et seq. and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 1 et seq. and associated federal regulations thereunder to the facts and circumstances presented herein constitute a federal question over which this Federal District Court exercises original jurisdiction under 28 USC Section 1331.

190. Plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC d/b/a NY Spine hereby demand judgment against defendants Orthogen International GmbH ("Orthogen") and United States Food and Drug Administration ("FDA") that this United States District Court and not the Courts of Germany has jurisdiction over the controversies stated herein.

191. WHEREFORE, Plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC d/b/a NY Spine hereby demand judgment against Defendants Orthogen International GmbH ("Orthogen") and United States Food and Drug Administration ("FDA") declaring that

a. FDA is not required under applicable law and regulations to determine whether or not Regenokine® is a drug, pharmaceutical or other modality subject to its administrative oversight and regulation through its Center for Biologics Evaluation and Research ("CBER"), and

b. The autologous procedures utilized in the administration of the Regenokine Program and drug to patients in drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood will not subject the Plaintiffs to any criminal or civil liability.

THE CAUSES OF ACTION

192. To the extent necessary to support each of the causes of action hereinafter set forth and alleged, Plaintiffs repeat and reallege the appropriate foregoing paragraphs of this Complaint commencing with the Section designated "Preliminary Statement," ¶ 17 and concluding with the final paragraph of the Section "Substantial Federal Question Concerning Orthogen and Regenokine® Regulation" ¶ 189. .

Tortious Interference with Plaintiffs' Advantageous Business Relationship and Contract Against the Orthogen Defendants

193. Plaintiffs repeat and reincorporate the above paragraphs as if fully set forth herein.

194. On or about March 24, 2020, the Orthogen defendants in conspiracy with the defendant Capla, and his wife, defendant Y. Capla, and with specific intent to do so,

wrongfully terminated the perennial License for the Regenokine® Program issued to plaintiff Dr. Schottenstein and defendant Capla not on any "for cause" basis, but on the sole basis that the License was not being renewed.

195. At all times pertinent to this illegal action and the underlying conspiracy by and between the Orthogen defendants and the Capla defendants, Orthogen and the other Orthogen defendants knew that that they were tortiously interfering with plaintiffs' economically advantageous relationship and contract with the Capla defendants that would result in losses to plaintiffs over time in the millions of dollars.

196. Plaintiffs had the existence of a valid contract by and between them and defendant Capla, as evidenced by the 2014 Regenokine License Agreement and the course of dealing over the eight (8) years that Dr. Schottenstein and defendant Capla conducted the Regenokine Practice. This contract was known to the Orthogen defendants, who had reason to know of the existence of same.

197. The Orthogen defendants intended to interfere with Plaintiffs' business relations with defendant Capla. In doing so, the Orthogen defendants commenced to conspire with the Capla defendants to interfere with said contract between Plaintiffs and defendant Capla, and thereby deny plaintiffs the economic benefits of that contract and their ownership interest in the Regenokine Practice.

198. The Orthogen defendants further acted fraudulently to cover up said tortious interference and conspiracy and thereby prevent plaintiffs from taking action to challenge and remediate the effect of these actions.

199. The Orthogen defendants intended to procure the breach of the contract with Plaintiffs by defendant Capla and thereby interfere with Plaintiffs' business relations without justification.

200. Within days after the discontinuance of the Regenokine® Program License Agreement with Schottenstein and Capla, Orthogen in furtherance of the aforesaid conspiracy and its tortious interference entered into a new Regenokine® Program License Agreement with Dr. Wasserman and defendant Capla to the exclusion of plaintiffs, who were unjustly regarded by the Orthogen defendants as *persona non grata.*

201. In conspiracy with the other Orthogen defendants and the Capla defendants, defendant P. Wehling actively and knowingly engaged in fraudulent communications with Dr. Schottenstein with the specific intent to mislead Dr. Schottenstein, prevent him from learning of the foregoing conspiracy, and causing him to withhold action challenging the License non-renewal and thereby losing the opportunity to remediate the damages willfully being caused.

202. Defendant Breidenbach actively conspired with the other Orthogen defendants and the Capla defendants with the express intent to interfere with Plaintiffs' economically advantageous relationship with defendant Capla, and through fraudulent actions and/or omissions to deprive Plaintiffs of the revenues under that relationship.

203. Breidenbach joined in the conspiracy to disrupt the economically advantageous relationship that Plaintiffs enjoyed with the Capla defendants by issuing the March 24, 2020 false letter terminating the perennial License

held by plaintiff Dr. Schottenstein and defendant Capla, and thereafter participated in the fraudulent conduct with the other Orthogen defendants to terminate that relationship and fulfill the objectives of the conspiracy by issuance of a new License to Dr. Wasserman and defendant Capla, excluding plaintiffs without legal or factual justification.

204. Thereafter, the Orthogen defendants demanded that plaintiff Dr. Schottenstein identify, turnover and/or transfer to defendant Capla, and Dr. Wasserman the patients that Plaintiffs had actively treated under the Regenokine® Program, thereby depriving Dr. Schottenstein of not only millions of dollars in revenue but also extraordinary damage to his professional reputation with these patients.

205. In furtherance of the foregoing conspiracy with the other Orthogen defendants and the Capla defendants, on August 3, 2022, defendant Niederau signed and delivered a letter to Dr. Schottenstein refusing to provide any know-how or services under the Regenokine® Program, stating "that there is no valid licensing agreement between you [Dr. Schottenstein] and ORTHOGEN," and demanding that Dr. Schottenstein refrain from any offer of the Regenokine® Program to his patients and to immediately take other specifically designated actions to disassociate from the Program.

206. The Orthogen defendants purposefully interfered with plaintiffs' economic advantage in the Schottenstein-Capla agreement by wrongful means and/or acted for the sole purpose of grievously harming plaintiffs.

207. The Orthogen defendants intended to and did interfere with Plaintiffs' business relations and procured the breach of the Schottenstein-Capla contract by defendant Capla without justification.

208. In wholly disrupting and defeating plaintiffs' economic advantage as described above, the Orthogen defendants intentionally acted with fraud, engaged in multiple and knowingly false misrepresentations with the intent that Dr. Schottenstein rely upon them to his detriment, and conspired with specific intent to accomplish their wrongful goals.

209. The Orthogen defendants, individually and collectively, knew and had reason to know that their actions causing the aforesaid interference and the breach by Defendant Capla of his contract with Plaintiffs were without justification and were specifically calculated to harm Plaintiffs..

210. The Orthogen defendants, individually and collectively, acted to achieve a wrongful purpose or used dishonest, unfair, or improper means to do so.

211. As a result Plaintiffs have suffered damages resulting therefrom.

212. WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, and Peter Niederau for compensatory and punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

Fraud Against the Orthogen Defendants and the Capla Defendants

213. Plaintiffs repeat and reincorporate the above paragraphs as if fully set forth herein.

214. The Orthogen defendants and the Capla defendants made deliberate and knowing false statements of current facts with the intention that Plaintiffs would rely thereon, and upon which Plaintiffs did justifiably so rely to their detriment thereby constituting fraud. These Defendants, individually and collectively knew that their statements and representations were false, and knew or had reason to know that such statements would induce Plaintiffs to rely upon them.

215. On or about March 24, 2020, defendant Orthogen acting through defendant Breidenbach, then Managing Director, and fully supported by defendant P. Wehling, issued a letter to Dr. Schottenstein and defendant Edward L. Capla advising that the License under the Regenokine® Program was to be terminated by May 31st, 2020 on the basis of non-renewal in accordance with the June 1st, 2014 License Agreement. The letter did not refer to any for cause basis for the termination.

216. This March 24, 2020 letter was issued to achieve the purpose of the conspiracy between the Orthogen defendants and the Capla defendants. Moreover, although not mentioned in this letter, on information and belief, the arrangement to issue a new Regenokine® Program License to defendant Edward L. Capla and Dr. Wasserman to the exclusion of plaintiffs had already been agreed upon.

217. The March 24, 2020 letter constituted a knowing, false, deceitful and illegal action by defendants Orthogen and Breidenbach, issued in breach of the controlling Side Letter Agreement dated July 9, 2014 that converted the License to a perennial term without the need for renewal, and motivated by and with specific intent to further the conspiracy and achieve its goal of damaging plaintiffs.

218. Shortly after the receipt of the March 24, 2020 letter, defendant Y. Capla sent Dr. Schottenstein an intentionally fraudulent text message falsely confirming that the Capla Defendants were pursuing a non-medical opportunity and deliberately withholding information that they had negotiated a new Regenokine® Program License agreement with Orthogen to the exclusion of plaintiffs.

219. The purpose of this text message was to falsely assure plaintiffs that they had accepted the termination and to mislead plaintiff Dr. Schottenstein into believing that nothing had occurred to merit a challenge.

220. Defendant P. Wehling actively and knowingly engaged in fraudulent and deceitful communications with Dr. Schottenstein through which he informed Plaintiffs that the License termination was only temporary and that Plaintiff's License would be restored following on-going negotiations by Orthogen to sell a portion of its interest in Regenokine. Defendant P. Wehling specifically intended to mislead Dr. Schottenstein, prevent him from learning of the foregoing conspiracy, cause him to withhold action to challenge the License non-renewal, and thereby sacrifice the opportunity to remediate the damages willfully being caused.

221. In this regard, P. Wehling deliberately and fraudulently misinformed Dr. Schottenstein that the non-renewal of the License was merely the result of a change in Orthogen's internal policy to limit practice under the Regenokine® Program to German practitioners while Orthogen was engaging in discussions to sell all or a portion of the Regenokine® Program rights to third parties. P. Wehling also fraudulently and deceitfully misinformed Dr. Schottenstein that the License would be reissued to Capla and him promptly after the current negotiations were concluded.

222. On August 3, 2022, defendant Niederau signed and delivered a letter to Dr. Schottenstein refusing to provide any know-how or services under the Regenokine® Program, stating "that there is no valid licensing agreement between you [Dr. Schottenstein] and ORTHOGEN," and demanding that Dr. Schottenstein refrain from any offer of the Regenokine® Program to his patients and to immediately take other specifically designated actions to disassociate from the Program.

223. In preparing and sending this letter to Dr. Schottenstein, defendant Niederau acted knowingly with fraud , and fully ratified the conspiracy between and among the Orthogen defendants and the Capla defendants.

224. As intended by the Orthogen and Capla Defendants, Plaintiffs justifiably relied upon the fraudulent statements and omissions of said Defendants and were deceived to their detriment..

225. These Defendants, individually and collectively, knew that their statements and representations were false, and that such statements would induce Plaintiffs' reliance on them.

226. Plaintiff Dr. Schottenstein was falsely caused to believe that these Defendants were acting with his best interests in mind.

227. Consequently, Plaintiff Dr. Schottenstein was justifiably induced to rely upon these Defendants, individually and collectively, in managing his personal and business affairs thereby incurring and continuing to incur substantial damages.

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, Peter Niederau and against defendants Edward L. Capla and Yolanda Capla , jointly and severally, for compensatory damages and punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

Civil Conspiracy Against the Orthogen and Capla Defendants

228. Plaintiffs repeat and reincorporate the above paragraphs as if fully set forth herein.

229. The Orthogen and Capla Defendants, individually and collectively, formed an agreement and worked within a conspiracy, respectively utilizing fraud and tortious interference on the part of the Orthogen Defendants, and fraud and conversion on the part of the Capla Defendants, to deprive Plaintiff of monies, business relations, ownership of the Regenokine Practice, and opportunities.

230. The Orthogen and Capla Defendants agreed to cooperate in an effort for the Orthogen Defendants to enable the avoidance of exposing Regenokine to regulation by the FDA and for the Capla Defendants to enrich themselves. In this regard both the Orthogen and Capla Defendants sought to exclude Plaintiff Dr. Schottenstein from the Regenokine License and the Regenokine Practice and to damage Plaintiffs.

231. Defendants, individually and collectively, took concerted effort and actions within the conspiracy to harm the Plaintiffs and achieve their respective goals.

232. These Defendants committed overt acts in furtherance of their agreement.

233. As a result, Plaintiffs suffered substantial financial injury and damages.

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, Peter Niederau and against defendants Edward L. Capla and Yolanda Capla , jointly and severally, for compensatory damages and punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

234. Conversion Against the Capla DefendantsPlaintiffs repeat and reincorporate the above paragraphs as if fully set forth herein.

235. Plaintiff Dr. Schottenstein possessed ownership rights to the Regenokine Practice and business that he created,

including patient lists, which constituted his property over which he legally and rightfully exercised possession and control..

236. The Capla Defendants, individually and collectively exercised an unauthorized dominion over Plaintiffs' property and business interests thereby depriving Plaintiffs of their ownership, possession and control of same.

237. The aforesaid Defendants' actions converting the ownership and possession of Plaintiffs' aforesaid property without authorization from or compensation to Plaintiffs served to alter and deprive Plaintiffs of their business assets, relationships and opportunities. .

238. Further, these Defendants, individually and collectively, schemed to exclude Plaintiffs from working on patients that sought the Regenokine treatment and drug.

239. Plaintiffs were excised of their ability to make or exercise business opportunities because of said Defendants' individual and collective actions.

240. Further, Plaintiffs are entitled to prejudgment interest. See *Wells Fargo Bank, N.A. v. Nat'l Gasoline, Inc.*, 577 F. App'x 58, 61 (2d Cir. 2014) (summary order) (citing N.Y. C.P.L.R. § 5001(a)).

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants against defendants Edward L. Capla and Yolanda Capla , jointly and severally, for compensatory damages and punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

Breach of Contract Against Defendant Orthogen

241. Plaintiffs repeat and reincorporate the above paragraphs as if fully set forth herein.

242. Plaintiff Dr. Schottenstein had a valid contract with Defendant Orthogen, namely, the 2014 Regenokine License Agreement.

243. Plaintiffs performed their obligations in accordance with the terms of the contract.

244. .

245. The terms of the contract by and between Plaintiff Dr. Schottenstein and Defendant Orthogen constituted a complete writing.

246. Defendant Orthogen did wrongfully and illegally terminate the contract with Plaintiff Dr. Schottenstein and, accordingly, did breach the terms and conditions of the aforesaid contract.

247. Plaintiffs suffered substantial monetary damages in the millions of dollars by reason of Defendant Orthogen's breach of contract.

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendant Orthogen International GmbH for compensatory damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

Unjust Enrichment/Quantum Meruit against the Orthogen and Capla Defendants

248. Defendants repeat and reincorporate the above paragraphs as if fully set forth herein.

249. Defendants, individually and collectively, were unlawfully enriched at the Plaintiffs' expense.

250. Plaintiff Dr. Schottenstein placed the Orthogen and Capla Defendants in a position of trust.

251. Plaintiff Dr. Schottenstein performed services for Defendant Orthogen and Capla in good faith.

252. The Orthogen and Capla Defendants, individually and through the co-conspirators in this action, accepted said Plaintiff's services.

253. Plaintiff Dr. Schottenstein increased the value of Defendant Orthogen and the Capla Defendants through his use, investment of time and resources, and service rendered to the License Agreement and the Regenokine practice. These Defendants took advantage of their position of trust to usurp money, business, patients/clients and financial opportunities from said Plaintiff.

254. Plaintiffs expected to obtain compensation and value for the services rendered.

255. Further, Plaintiffs expected to retain their clients, financial gains, and profits from their investments and services.

256. Plaintiffs aver that it is against equity and good conscience to permit these Defendants to retain what is sought to be recovered.

257. Plaintiffs aver that they were denied reasonable value for the services they rendered.

258. Because these Defendants benefitted at Plaintiffs' expense, equity and good conscience requires restitution.

259. Accordingly, Plaintiffs have been damaged in an amount greater than $75,000, and such damages continue to date, together with reasonable costs, attorney's fees and all other relief that this Honorable Court deems just and proper.

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendants Orthogen International GmbH, and against defendants Edward L. Capla and Yolanda Capla , jointly and severally, for compensatory damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

Unjust Enrichment/Quantum Meruit claims require an Accounting and a Constructive Trust

260. Plaintiffs repeat the above allegations as if fully set forth herein.

261. Defendants Orthogen and Capla have each entered into separate confidential and/or fiduciary relationships with plaintiff Dr. Schottenstein.

262. Orthogen entered into this relationship with Dr. Schottenstein in or about 2012 in the form of a Regenokine® Program License Agreement with a renewable term, which License Agreement was renewed in or about June, 2014 and thereafter modified with a

perennial term that required no renewals and could only be terminated for cause.

263. Commencing in or about 2012, Capla entered into an agreement with Dr. Schottenstein constituting a confidential and fiduciary relationship by reason of Capla's acceptance of a Regenokine® Program License designating him as Licensee No. 2 that was subordinate to and under the supervision of Dr. Schottenstein as Licensee No. 1, but contained together with their subsequent 8 year course of dealing their agreement regarding the operation of the Regenokine Practice with allocation of revenues to Plaintiffs and payment of compensation to Capla for the services they rendered.

264. Under the terms of the Regenokine® Program License Agreement, defendant Orthogen promised Dr. Schottenstein that he would enjoy the benefits of said Agreement and the revenue generated thereunder in accordance with the terms of that Agreement.

265. In accordance with their agreement concerning the conduct of the Regenokine® Program practice, defendant Edward L. Capla and Dr. Schottenstein entered into mutual promises with the other to conduct their activities thereunder in good faith and with recognition of their fiduciary duties each to the other.

266. Dr. Schottenstein expended money, labor and time both under the Regenokine® Program License Agreement with Orthogen, and in regard to the agreement with defendant Edward L. Capla. These expenditures benefitted both Orthogen and Capla within their respective agreements with Dr. Schottenstein, and these expenditures constituted

a transfer of value to each of the aforesaid defendants in reliance by plaintiffs thereon.

267. Defendant Orthogen acted with fraud , and defendant Capla breached their respective fiduciary duties and duties of loyalty by Orthogen wrongly terminating the 2014 License Agreement in breach thereof and the Capla Defendants converting the Regenokine Practice and accepting a new Regenokine License excluding Dr. Schottenstein.

268. An accounting is appropriate under these circumstances due to Orthogen's wrongful termination of Plaintiff Dr. Schottenstein's Regenokine License, the usurpation and conversion of the Regenokine Practice by the Capla Defendants, the loss of Regenokine patients assigned to Dr. Schottenstein, the resulting patient confusion and the conversion and appropriation of these items by the Capla Defendants. See Dependable Sales & Service, Inc. v. Truecar, Inc., No. 15-cv-1742 (PKC) (S.D.N.Y. July 12, 2019); Int'l Star Class Yacht Racing Ass'n v. Tommy Hilfiger U.S.A., Inc., 146 F.3d 66, 72 (2d Cir. 1998)

269. Without the intervention of this Honorable Court, these Defendants will be unjustly enriched.

270. In reliance on the representations of these Defendants, Plaintiffs did entrust these Defendants with monies, propriety and business information and proceeds from Plaintiffs' Regenokine Practice and the Regenokine treatment.

271. Defendants were unjustly enriched at Plaintiffs' expense and to Plaintiffs' detriment.

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand judgment against defendant Orthogen International GmbH and against defendants Edward L. Capla and Yolanda Capla , jointly and severally, for compensatory damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

Injunctive Relief against Orthogen Defendants from continuing litigation in Germany;

272. Plaintiffs reincorporate the above paragraphs as if fully set forth herein.

273. "A party seeking a preliminary injunction must ordinarily establish (1) irreparable harm; (2) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; and (3) that a preliminary injunction is in the public interest." New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 650 (2d Cir. 2015).

274. To obtain a preliminary injunction, a party need only demonstrate likelihood of success on one claim against each defendant. See Eatery Corp. v. City of New York, 408 F. Supp. 3d 424, 459 (S.D.N.Y. 2019).

275. By letter dated November 28, 2022 from legal counsel, Orthogen, first contended that the March 24, 2020 letter effectively terminated Dr. Schottenstein's License, a position that wholly ignores the admissions binding Orthogen that the Schottenstein License was never

terminated and had been fully reinstated, then asserted that the reinstated License was terminated once again, this time for cause.

276. In that letter, defendant Orthogen through its legal counsel threatened to commence litigation against plaintiffs in the court of Duesseldorf, Germany. Subsequently, Defendant Orthogen did initiate that litigation as threatened but after Plaintiffs initiated this action first in New York Supreme Court under Index No. 654562/2022 on notice to Orthogen's counsel in Germany, raising substantially the same issues as set forth by Plaintiffs herein, and to which this Complaint relates back.. Consequently, Plaintiffs were the first to file and Orthogen was specifically aware of same.

277. Plaintiffs seek injunctive relief from this Court to stay defendant Orthogen and the other Orthogen defendants from proceeding with such litigation in Germany, considering that this case includes the United States Food and Drug Administration as a defendant in order to address and resolve the federal questions that underlie all claims asserted herein as well as those claims involving the Orthogen defendants and the Capla defendants comprising all of the parties needed to resolve the claims set forth hereunder, and where this matter also addresses under this Court's diversity jurisdiction claims based upon tortious interference, fraud and deceit, breach of fiduciary duty, breach of the duty of loyalty, conspiracy, conversion, an accounting, unjust enrichment and constructive trust to remedy the wrongful acts that occurred within the jurisdiction of this Court.

278. The facts set forth in this matter demonstrate a likelihood of success for plaintiffs on the merits in that Orthogen issued the March 24, 2020 termination notice to Dr. Schottenstein not due to oversight or mistake, but with an intention to both evade federal regulatory jurisdiction as well as to tortiously interfere with the economically advantageous relationship with defendant Edward L. Capla that can no longer be resurrected.

279. The Orthogen defendants and the Capla defendants conspired with fraud and other tortious conduct and with specific intent to damage plaintiffs economically and in their reputation.

280. The participation of the Orthogen defendants in that conspiracy enabled the tortious interference with the Schottenstein-Capla agreement and further enabled defendant Edward L. Capla and Dr. Wasserman to convert the Regenokine® Program practice in which Dr. Schottenstein owned at least 50%.

281. Proceeding with an action in Germany pursuant to the forum selection provision contained in the License Agreement presents Plaintiffs with irreparable harm due to the grave unfairness of the selected forum in Germany that will prevent plaintiffs from asserting any of the claims set forth in this matter thereby denying plaintiffs their day in court and a remedy constituting unconscionable and grave unfairness of the selected forum under that provision. Furthermore, the transfer of this matter to the German court will violate the strong policy of protecting the health, safety and welfare of American citizens when the implications of a matter most directly

affects them, as they do regarding the federal questions asserted.

282. The Orthogen Defendants have conceded that this District is the locus of this litigation having already relied upon the jurisdiction of this Court in filing a Section 1782 Petition seeking leave to issue subpoenas for documents and deposition testimony for the litigation in Germany. Moreover, Orthogen will most likely return to this District should it require enforcement of any judgment that it may achieve.

283. In addition, claims are asserted in this matter, such as fraud, conversion, tortious interference, accounting and constructive trust, which are beyond the scope of the License Agreement which is the condition precedent for the forum selection provision to apply.

284. The Orthogen defendants will have a full and fair opportunity to litigate all of the issues posed in this Complaint and the further opportunity to assert a counterclaim if and as desired by them.

285. Under the foregoing considerations, the equities balance in favor of the plaintiffs to preserve the status quo while these issues are litigated within this matter as filed.

WHEREFORE, plaintiffs Douglas Schottenstein, MD and Schottenstein Pain and Neuro, PLLC doing business as NY Spine, demand the issuance of a preliminary injunction barring defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, and Peter Niederau or any one or more of them from proceeding with litigation in Germany against plaintiffs thereby requiring them to litigate

all issues in this Court together with such other relief as this Court may deem necessary or just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment which will:

DECLARE JURISDICTION over Orthogen in this United States District Court and not a Court of Foreign Jurisdiction to determine common issues of fact and law;

ENJOIN Orthogen from litigating common issues of law and fact pertaining to this lawsuit in a Court of Foreign Jurisdiction;

DECLARE SUBSTANTIAL FEDERAL QUESTION JURISDICTION insofar as the US FDA is not required under applicable law and regulations to determine whether or not Regenokine® is a drug, pharmaceutical or other modality subject to its administrative oversight and regulation through its Center for Biologics Evaluation and Research ("CBER"), and

DECLARE SUBSTANTIAL FEDERAL QUESTION JURISDICTION that the autologous procedures in drawing blood from patients with inflammation from trauma or other causes, treating that blood with proprietary substances and processes and then reintroducing that blood are now before the US FDA insofar as their interests appear and that Plaintiffs provide this treatment to the US FDA in accordance with the Hippocratic Oath in the absence of criminal or civil liability relating to the administration of the Regenokine® treatment that this Honorable Court found has been in use for over a decade.

ISSUE AN ACCOUNTING of all revenues, patients, procedures, records and royalty payments to Orthogen from and after May 31, 2020 to and through the current date and thereafter until further order of this Court,

ISSUE A CONSTRUCTIVE TRUST of same, and against defendant Orthogen for the establishment and imposition of a constructive trust for all funds derived from the aforesaid Capla-Wasserman Regenokine® Program practice and/or any other such practice located within New York State that would otherwise be payable to defendant Orthogen as royalties or other fees commencing on and after May 31, 2020 and continuing thereafter until further order of this Court;

PROHIBITING Orthogen Defendants, individually and collectively, from terminating Plaintiffs' business interests and License, interfering with the patient-physician relationship that Plaintiff Dr. Schottenstein has with Regenokine patients that he has previously treated, or usurping plaintiffs' patients, proprietary interests, money and other resources;

AWARD, on the above causes of action, judgment against defendants Orthogen International GmbH, Prof. Dr. Peter Wehling, Nina Breidenbach, Peter Niederau, Edward L. Capla and his wife Yolanda Capla, for compensatory damages and punitive damages together with attorneys' fees, costs of suit, and such other and further relief as this Court may find equitable and just.

AWARD all costs, including costs and attorneys' fees, and the costs of prosecuting this action to the fullest extent allowed by law.

All together with such other and further and additional relief as this Court may deem just and proper.

DATED AT Huntington, N.Y.
July 20, 2023

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INDEPENDENT VERIFICATION

State of New York
New York County } *ss*:

Douglas Schottenstein, MD, a licensed medical doctor duly affirming under the penalty of perjury deposes and says that I am the Plaintiff(s) filing this Amended Verified Complaint; that I have read the foregoing Amended Verified Complaint and know the contents thereof; that the same is true to deponent's own knowledge, except as to the matters therein stated to be alleged on information and belief.

Duly affirmed under penalty of
perjury on July , 2023

_____
Douglas Schottenstein

Sworn before me
on the ___ of
July, 2023

_____
NOTARY PUBLIC